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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR		ATTORNEY DOCKET NO.
09/420,695	10/19/99	THANAVALA	Y	RPP:156A-US

HM12/0129

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EXAMINER	
FLOOD,M	
ART UNIT	**PAPER NUMBER**
1651	16

DATE MAILED: 01/29/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Advisory Action

Application No.	Applicant(s)
09/420,695	Thanavala et al.
Examiner	**Group Art Unit**
Michele Flood	1651

THE PERIOD FOR RESPONSE: [check only a) or b)]

a) ☒ expires 3 months from the mailing date of the final rejection.

b) ☐ expires either three months from the mailing date of the final rejection, or on the mailing date of this Advisory Action, whichever is later. In no event, however, will the statutory period for the response expire later than six months from the date of the final rejection.

Any extension of time must be obtained by filing a petition under 37 CFR 1.136(a), the proposed response and the appropriate fee. The date on which the response, the petition, and the fee have been filed is the date of the response and also the date for the purposes of determining the period of extension and the corresponding amount of the fee. Any extension fee pursuant to 37 CFR 1.17 will be calculated from the date of the originally set shortened statutory period for response or as set forth in b) above.

☐ Appellant's Brief is due two months from the date of the Notice of Appeal filed on _____ (or within any period for response set forth above, whichever is later). See 37 CFR 1.191(d) and 37 CFR 1.192(a).

Applicant's response to the final rejection, filed on *Jan 4, 2001* **has been considered with the following effect, but is NOT deemed to place the application in condition for allowance:**

☒ The proposed amendment(s):

☒ will be entered upon filing of a Notice of Appeal and an Appeal Brief.

☐ will not be entered because:

☐ they raise new issues that would require further consideration and/or search. (See note below).

☐ they raise the issue of new matter. (See note below).

☐ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal.

☐ they present additional claims without cancelling a corresponding number of finally rejected claims.

NOTE: _____

☐ Applicant's response has overcome the following rejection(s):

_____

☐ Newly proposed or amended claims _____ would be allowable if submitted in a separate, timely filed amendment cancelling the non-allowable claims.

☒ The affidavit, exhibit or request for reconsideration has been considered but does NOT place the application in condition for allowance because:
See attached paper.

☐ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.

☒ For purposes of Appeal, the status of the claims is as follows (see attached written explanation, if any):

Claims allowed: _____

Claims objected to: _____

Claims rejected: *1 and 4-18*

☐ The proposed drawing correction filed on _____ ☐ has ☐ has not been approved by the Examiner.

☐ Note the attached Information Disclosure Statement(s), PTO-1449, Paper No(s). _____ .

☐ Other

DETAILED ACTION

Acknowledgment is made of the receipt of Applicant's response made under 37 CFR 1.111 and 1.113.

Full consideration has been given to Applicant's arguments and declaration, however, Applicant's arguments do not distinguish over the prior art of record. Applicant argues that the rejection of Claims 1 and 4-18 made under 35 U.S.C. 103 as being unpatentable over Arntzen et al. in view of Koprowski et al., and further in view of Stites et al. is a new rejection, and therefore should be removed. However, this is not found persuasive because the substantial amendment of the claims by Applicant necessitated the adjustment in the rejection. Thus, the rejection made in the previous office action is maintained.

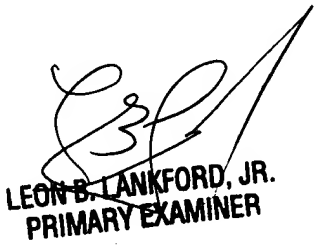
Applicant urges that the teachings of Arntzen provide no data for raising an immune response by ingestion, and that the ingestion of the transgenic tomato taught by Arntzen, as evidenced by the Declaration of Dr. Yasmin Thanavala, does not raise any significant immune response. Applicant concludes that the patent of Arntzen does not provide any suggestion or teaching to the claimed invention. Contrary to Applicant's arguments, Arntzen clearly teaches an anti-viral vaccine produced in transgenic plants, wherein the vaccine is administered through the consumption of an edible plant, such as the tomato or the potato, preferably in the form of a fruit or vegetable juice or through standard vaccine procedure. Moreover, Arntzen specifically teaches methods of making a transgenic plant expressing an immunogen derived from hepatitis B surface

antigen, wherein the immunogen is capable of eliciting an immune response in an animal by consumption of the plant material.

Applicant further argues that Anrtzen discloses or suggest no way in which a high immune response could be orally obtained, and that the teachings of Koprowski and Stites do not reasonably suggest the claimed invention. However, Applicant's arguments are not deemed persuasive. With Arntzen expressly teaching that the physiologically acceptable plant materials expressing hepatitis B surface antigen could be used to both prime the mucosal immune system and/or stimulate the humoral immune response in a dose dependent manner and with Koprowski teaching the oral delivery of plant material expressing a viral antigen in combination with an adjuvant, it would have been obvious to one of ordinary skill in the art to provide a method for providing a serum IgM and IgG response specific to hepatitis B surface antigen because it was old and well-known in the art at the time the invention was made that the delivery of a vaccine or therapeutic compound with an adjuvant facilitates and improves its immunological therapeutic activity in an individual, as evidenced by the teachings of both Koprowski and Stites.

Thus, the claimed invention was prima facie obvious to one of ordinary skill in the art at the time the invention was made especially in the absence of evidence to the contrary.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michele Flood whose telephone number is (703) 308-9432. Any inquiry of a general nature or relating to the status of this application should be directed to the Group 1600 receptionist whose telephone number is (703) 308-0196 or the Supervisory Patent Examiner, Michael Wityshyn whose telephone number is (703) 308-4743.



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January 25, 2001